Complete Summary

GUIDELINE TITLE

Thrombocytopenia in pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Thrombocytopenia in pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 Sep. 12 p. (ACOG practice bulletin; no. 6). [72 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On January 6, 2006, Cangene, Baxter Healthcare and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revisions to the WARNINGS, PRECAUTIONS and ADVERSE REACTIONS sections of the prescribing information for WinRho SDF (Rho[D] Immune Globulin Intravenous [Human]) to address two important safety concerns.

1. Postmarketing safety surveillance has shown rare, but severe and sometimes fatal, intravascular hemolysis and potentially serious complications, including disseminated intravascular coagulation in patients with ITP.
2. Maltose in IVIG products, such as the liquid formulation of WinRho SDF, has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in patients receiving this product.

See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Thrombocytopenia in pregnancy

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Hematology
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide recommendations regarding management of women with thrombocytopenia in pregnancy

TARGET POPULATION

Pregnant women with thrombocytopenia

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

Differential diagnosis of thrombocytopenia in pregnancy including:

1. Detailed medical and family history
2. Physical examination
3. Laboratory tests such as complete blood count (CBC) and peripheral blood smear

Management

Immune Thrombocytopenic Purpura (ITP)

1. Prednisone
2. Intravenous immune globulin (IVIG)
3. Splenectomy if needed
4. Platelet transfusion
5. Instructing women with ITP to avoid nonsteroidal anti-inflammatory agents, salicylates, and trauma
6. Immunization against pneumococcus, Haemophilus influenzae, and meningococcus in patients with splenectomy
7. Experienced specialist consultation and ongoing evaluation

Neonatal Alloimmune Thrombocytopenia

1. Evaluation of patients with history of infants with otherwise unexplained bleeding or thrombocytopenia
2. Laboratory evaluation including platelet types and zygosity of both parents, confirmation of maternal antiplatelet antibodies with specificity for paternal (or fetal-neonatal) platelets and the incompatible antigen, and platelet typing

   Note: Population-based screening for platelet antigen incompatibility was considered but not recommended

3. Individualized management decisions
4. Consultation with obstetric and pediatric specialists
5. Fetal platelet count
6. Antepartum maternal intravenous IVIG, with or without steroids
7. Fetal platelet transfusion
8. Cesarean delivery for cases with severe thrombocytopenia

Gestational Thrombocytopenia

1. Follow-up platelet counts

Thrombocytopenia Associated with Pregnancy-Induced Hypertension (PIH) or Hemolysis, Elevated Liver Enzymes, and Low Platelet Counts (HELLP) Syndrome

1. Platelet transfusion
2. Plasma exchange in women with HELLP syndrome
3. Delivery

MAJOR OUTCOMES CONSIDERED

- Platelet counts
- Risk of complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 1999. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Neonatal alloimmune thrombocytopenia should be treated with intravenous immune globulin (IVIG) as the initial approach when fetal thrombocytopenia is documented.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- The mode of delivery in pregnancies complicated by immune thrombocytopenic purpura (ITP) should be chosen based on obstetric considerations alone. Prophylactic cesarean delivery does not appear to reduce the risk of fetal or neonatal hemorrhage.
- Epidural anesthesia is safe in patients with platelet counts greater than 100,000/microliter.
- Mild maternal thrombocytopenia ($\geq$70,000/microliter) in asymptomatic pregnant women with no history of bleeding problems is usually benign gestational thrombocytopenia. These women should receive routine prenatal care with periodic repeat platelet counts (monthly to bimonthly).

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Platelet counts of at least 50,000/microliter rarely require treatment.
- Neonatal alloimmune thrombocytopenia should be suspected in cases of otherwise unexplained fetal or neonatal thrombocytopenia, hemorrhage, or porencephaly.
- Prior to initiating any plan of treatment for a woman based on thrombocytopenia in her fetus, consultation should be sought from a physician with experience dealing with that problem.
- Laboratory testing for neonatal alloimmune thrombocytopenia should be performed in a regional laboratory with special interest and expertise in dealing with the problem.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved diagnosis and management of thrombocytopenia in pregnancy

POTENTIAL HARMS

- Splenectomy is associated with fetal risks and technical difficulties late in gestation, but can be accomplished safely during pregnancy, ideally in the second trimester.
- The laboratory evaluation of neonatal alloimmune thrombocytopenia can be complex, results may be ambiguous, and an antigen incompatibility cannot always be identified.
- Platelet transfusion requires weekly procedures because of the short half-life of transfused platelets, and may worsen alloimmunization.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Sep (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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